URGENT: PRODUCT RECALL

Cardinal Health
1430 Waukegan Road
McGaw Park, IL 60085
800.292.9332 toll free

www.cardinal.com

CardinalHealth

July 20, 2006

Re: Catalog No: 43160-990
Vendor No: 85863
Lot #' s: Beginning with 05 and 06

Description: Mallinckrodt® Satin-Slip® Intubating Stylets, 6Fr

Dear Director of Materials Management:

Cardinal Health has recently been informed by Nellcor /Tyco Healthcare that their **Mallinckrodt® Satin-Slip® Intubating Stylets, 6Fr** are being recalled because sheath material may separate and become lodged in the patients endotracheal tube or respiratory track. (See enclosed notice).

Cardinal Health has completed its investigation of this notice and our records indicate that you may have been shipped product affected by the Nellcor/Tyco Healthcare recall.

If you are a hospital, please contact Cardinal Customer Service at 800-964-5227 to arrange for product return and credit or replacement. All other customers should call 1-888-444-5440 for product return and replacement.

Please return the enclosed acknowledgment form via fax to 847-689-9101, whether or not you have affected product, as Cardinal Health is required to confirm receipt of this notification by our customers.

We sincerely apologize for any inconvenience this notice may have caused you and your staff. Should you have any questions or desire special assistance relating to this recall, please feel free to contact Cardinal Health Quality Systems, 1-800-292-9332.

Sincerely,

Ruben Ortiz
Quality Systems Analyst
FCA 2006226

tyco
Healthcare

Nellcor

4280 Hacienda Drive
Pleasanton, CA 94588

Tele: 925 463-4000
Fax: 925 463-4420

July 12, 2006

URGENT PRODUCT RECALL
Mallinckrodt® Satin-Slip® Intubating Stylets, 6 Fr.
Part Number 85863

Dear Valued Nellcor Customer:

Tyco Healthcare / Nellcor has recently received a number of reports regarding the plastic sheath material separating from Mallinckrodt Satin-Slip Intubating Stylets, size 6 Fr., part number 85863. While the rate of this occurrence is low, if sheath separation occurs the sheath material may become lodged in the patient's endotracheal tube or respiratory tract, requiring medical intervention. While we investigate the root cause of the sheath material separation, we have elected to recall all size 6 Fr. Satin-Slip Intubating Stylets, part number 85863, with lot codes beginning with the numbers 05 or 06.

We recommend that your facility immediately cease use of the 6 Fr. Satin-Slip Intubating Stylet, part number 85863, with lot codes beginning with 05 or 06, and remove all such products from your facility's inventory.

To assist you in the return of any affected stylets that are new and in their original packaging, a Returned Goods Authorization (RGA) number has been created for your facility, and is printed on this letter. Once you have removed all affected stylets from inventory, please complete the enclosed form, and fax it to our Technical Services department at 1-925-463-4720. A credit will be issued for all affected returned stylets following receipt. Please do not return any product for credit without first completing and faxing the form, as this may delay receipt and your credit. If you have no affected product in stock, please take a moment to complete and fax the form so that we may track the effectiveness of this recall.

If you or your facility has distributed the 6 Fr. Satin-Slip Intubating Stylet to other persons or facilities, please promptly contact the recipients of the devices and provide them with information regarding this action. It is important to note that 10 Fr. and 14 Fr. sizes of the Satin-Slip Intubating Stylet are not affected by this action.

Please note, as discussed in the Mallinckrodt Satin-Slip Intubating Stylet Directions for Use, all sizes of Mallinckrodt Satin-Slip Intubating Stylets are single-patient use devices, and should be discarded following single use. Do not attempt to re-use any size of Mallinckrodt Satin-Slip Intubating Stylets.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

As we are actively investigating this matter, we cannot predict when we expect to have the 6 Fr. Satin-Slip Intubating Stylet available. We are committed to providing you and your patients with the highest quality products and services and apologize for the inconvenience that this matter may cause. We greatly appreciate your cooperation and understanding as we work to resolve this issue. If you have any questions regarding this matter, please contact Technical Services at 1-800-635-5267, press 3, or your local Nellcor Sales Representative.

Sincerely,

Michael W. Doran

Michael W. Doran
Vice President
Quality Assurance

CUSTOMER ACKNOWLEDGMENT FORM
Nellcor
RECALL NOTICE DATED: 07/20/2006

Dear Quality Systems-Professional Services Department:

This is to acknowledge that we have received your communication, concerning the above referenced action. We have reviewed the documentation and are providing you with the following checked information:

INVENTORY SECTION

☐ We have affected inventory within our possession.

Quantity of product remaining within our facility_____

☐ We have no affected inventory within our possession.

Print name of person completing this form_____

Print Institution Name, City, State, Zip_____

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If your facility is a member of a health system or group operation, please identify on this line:

_____

Please return this form via fax to 1.847.689.9101 or 1.847.578.4252
File No.2006226